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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,898	OPHEIM, JOAR	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/21/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's RCE filed 01/16/2009; and IDS filed 01/21/2009.

Claims 1-9, and 14-16 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/16/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-9, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with the article "Encyclopedia of Pharmaceutical Technology", provided by applicant in the IDS filed 01/21/2009, US 5,955,102 ('102), and US 5,718,323 ('323).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of capsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process. The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of capsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule.

The article "Encyclopedia of Pharmaceutical technology" teaches that the flavor can be included in the shell in small amount (page 287). The article further teaches that

the shell contain 5-10% water after drying and teaches that increasing the water content results in making the capsules more soft and stick together and may leak affecting potency of the capsule (pages 276-279).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soft gelatin capsule coated with flavored shell containing gelatin, plasticizer, flavor and water as disclosed by Lachman and adjust the amount of water to between 5-10% as disclosed by the article "Encyclopedia of Pharmaceutical technology". One would have been motivated to do so because "Encyclopedia of Pharmaceutical Technology" teaches that decreasing the water content in the shell to between 5-10% water and teaches that higher water content results in making the capsules more soft and sticking together and may leak affecting potency of the capsule. One would have reasonably expected formulating soft gelatin capsules having flavored shell containing 5-10% water wherein the capsules are not sticking together nor leaking and have extended potency.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules combined with flavoring agents.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide shell of gelatin capsule as disclosed by Lachman that comprises gelatin, softener, 5-10% water and small amount of flavor as disclosed by the combination of Lachman and the article "Encyclopedia of

Pharmaceutical Technology", and use the capsule to deliver fish oil as disclosed by US '102. One would have been motivated to do so because US '102 teaches that the gelatin capsules are the preferred delivery method for the fish oil. One would have been reasonably expected formulating a gelatin capsule filled with fish oil and having shell containing gelatin, softener, 5-10% water and small amount of flavoring agent to successfully provide fish oil in pleasant form to the patient in need of such a nutrient.

The combination of Lachman, the article "Encyclopedia of Pharmaceutical Technology" and US '102 does not explicitly teach water-soluble fruit flavors.

US '323 teaches soft gelatin capsule shell comprising flavoring agent selected from essential oils and fruit flavor or combinations thereof (col.5, lines 43-49). Examples C9 and C10 showed lemon flavor, as instantly claimed. Fruit flavors are expected to be water-soluble since compounds and their properties are inseparable.

Therefore, the prior art recognized gelatin capsules with flavored shell, and also recognized the equivalency as well as the combination of essential oil flavors and fruit flavors.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent and 5-10% water to impart the desired taste as disclosed by the combined teaching of Lachman, "Encyclopedia of Pharmaceutical Technology" and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323. One would have been motivated to do so because US '323 desired to add essential oil or fruit flavors, or their

combination, to the shell of gelatin capsule, and because US '323 further preferred and exemplified lemon flavor. One would have reasonably expected formulating gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor and specially lemon flavor, and 5-10% water, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

Regarding claims 8 and 9, it is known in the art to flavor the contents of the gelatin capsule as disclosed by the article "Encyclopedia Pharmaceutical Technology" and by US '323, and one having ordinary skill in the art at the time of the invention would have flavored the oily material encapsulated in the gelatin capsule with oily flavor to ensure its solubility in the capsule contents.

Response to Arguments

4. Applicant's arguments filed 01/16/2009 have been fully considered but they are not persuasive.

Applicant argues that Lachman does not teach water soluble flavor and US '323 teaches fruit flavors which are not clear if they are water soluble. US '323 does not teach the claimed concentration of the flavor, and teaches away from the claimed amounts.

In response to the above argument, it is noticed that applicant argues against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Lachman teaches the flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule, and this is falls within the range of the claimed amounts of between 0.1 to 1.5. Lachman further teaches that the amount of flavoring is further reduced during drying of the capsule, and this teaching implies higher concentration of the flavoring agent in the shell of the capsule. US '323 is relied upon for teaching the fruit flavors in the capsule shell, and it teaches lemon flavor that is claimed by applicant and that is water soluble since compounds and their properties are inseparable. Therefore, the water soluble flavor in the capsule is taught by US '323 and further Lachman teaches the same amount as instantly claimed.

Regarding the argument that Us '323 teaches away, it is argued that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994). In the instant case, US '323 teaches and suggested addition of flavor in shell of soft gelatin capsule.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated

by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

Applicant further argues that the combination of the references does not teach all the elements of the claims and no reason to combine the references.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent including essential oil to impart the desired taste as disclosed by the combined teaching of Lachman and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323, motivated by the desire of US '323 to flavor the shell of gelatin capsule with essential oil or fruit flavors, or their combination, with lemon flavor exemplified as a preferred flavor, with reasonable expectation of having gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor, and specially lemon flavor, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that only hindsight guided by Applicant's disclosure guides the modification of the disclosure of the prior art to the selection of these particular elements recited by the instant claims, in direct contravention of binding precedent.

In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that the declaration under 37 CFR 1.132 filed 04/10/2006 and the declarations filed 09/25/2006 and 03/29/2007 are sufficient to overcome the nonobviousness rejection of the claims.

In response, it is notices that the objective evidences are insufficient to overcome the rejection of the claims based upon U.S.C. 103 (a) as set forth in the last Office action because: there was no showing that the objective evidence of nonobviousness as well as commercial success are commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in amounts of 0.1% to 1.5%, while the declaration is limited only to one flavor, lemon flavor, at specific concentration of 1.0% in the shell and 1.0% in the content of the capsule, even it mention range from 0.25-1.5%, but no showing of unexpected results of range as low as 0.25% or as high as 1.5%. No showing of effect of range below the lower range of claimed amount or over the upper range of the claimed amount to establish superiority of the results. Furthermore, no showing that the commercially successful product is the same as the claimed product. The species of the flavoring agent in specific concentration in the shell composition and specific amount in the content of the capsule of the declaration does not support the generic concept of the claims encompassing wide ranges and various flavors. There is no comparative data between the claimed amount of the flavor with amounts outside the upper and the lower ends of the claimed range. Objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in *Greenfield and DuPont* 197 USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88

(CCP 1971). The declaration includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611